DRAFT

Left Ventricular Assist Devices (LVAD) for Destination Therapy
Questions for the Medicare Coverage Advisory Committee (MCAC)
March 12, 2003

Voting Question (After discussion, each panelist will be asked to comment prior to voting)

Is the quality of the evidence adequate to draw conclusions about the net health outcomes in Medicare beneficiaries meeting the Randomized Evaluation of Mechanical Assistance for the Treatment of Heart Failure (REMATCH) trial criteria who undergo LVAD implantation?

Please consider the following in your assessment of the quality of the evidence:

- Are the study endpoints and patient selection criteria appropriate?
- Are the management and extent of complications adequately described?
- Do the follow-up survival data for the REMATCH trial suggest any meaningful difference in patient survival compared to the data at the time the study reached its primary endpoint?

If the quality of the evidence is adequate, does it demonstrate any positive net health outcomes and if so what is the size of the improvement in net health outcomes of LVADs compared to optimal medical management for these patients? (See MCAC document "Recommendations for Evaluating Effectiveness" for categories of effectiveness).

Discussion Questions (Each panelist will be asked to comment on each issue)

REMATCH showed increased survival in device recipients, but the survival advantage diminished over time and was associated with severe complications and increased hospitalization. Does the demonstrated extension of life and limited improvement in the quality of life justify the risks of LVAD implantation?

One REMATCH inclusion criterion was that a candidate for LVAD implantation for destination therapy could not be a heart transplant candidate. Should the evaluation to determine transplant candidacy be performed only by a heart transplant center that has been approved for Medicare reimbursement?

Initially, should there be specific facility (e.g. Medicare approved transplant center only or other transplant center) and personnel requirements (surgeon and team experience) that must be met to provide the patient with an optimal chance of successful LVAD implantation (e.g., adequate pre/post operative care, follow-up care, psychological support for patient/family, and end-of-life care)?

REMATCH results are based on LVAD implantation in 68 patients. Complete, timely, and accurate LVAD implant and outcomes data for destination therapy patients is critical to future Medicare coverage review and policy refinements. Should mandatory data reporting be required as a condition for Medicare reimbursement?

There have been improvements in both LVAD design and medical management of end-stage heart failure patients since the start of the REMATCH trial. Have these improvements affected the applicability of the REMATCH results?

"MCAC Categories of Effectiveness"

- *Breakthrough technology:* The improvement in health outcomes is so large that the intervention becomes standard of care.

- *Substantially more effective (approved 9/25/02):* The new intervention improves health outcomes by a substantial margin as compared with established services or medical items.

- *More effective:* The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.

- *As effective but with advantages:* The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.

- *As effective and with no advantages:* The intervention has the same effect on health outcomes as established alternatives but with no advantages.

- *Less effective but with advantages:* Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).

- *Less effective and with no advantages:* The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.

- *Not effective:* The intervention has no effect or has deleterious effects on health outcomes when compared with "doing nothing," (e.g., treatment with placebo or patient management without the use of a diagnostic test).